UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DANIKA GISVOLD,

Plaintiff,

vs.

MERCK & CO., INC. *et al.*,

Defendants.

Case No. 14cv1371 DMS (JLB)

ORDER GRANTING MOTION TO DISMISS

Pending before the Court in this putative consumer class action is Defendants' Merck & Co., Inc., MSD Consumer Care Inc., and Merck Sharp & Dohme Corp.'s (collectively "Merck Defendants" or "Merck") motion to dismiss the First Amended Complaint ("FAC"). Plaintiff Danika Gisvold filed an opposition and Defendants replied. The motion came on for hearing on November 4, 2014. James Patterson appeared on Plaintiff's behalf; David Stanley appeared on behalf of Defendants. Upon consideration of the briefing and oral argument, and for the reasons set forth below, Defendants' motion to dismiss is granted.

Plaintiff alleges the Merck Defendants are manufacturers, distributors and marketers of Coppertone over-the-counter ("OTC") sunscreen products, including products labeled with Sun Protection Factor ("SPF") 50 and above. (FAC ¶ 1.) Plaintiff claims she purchased Coppertone SPORT SPF 100+ sunscreen lotion at Wal-Mart for

a premium price ($1.00 or more than the same size SPF 50 product) after "reading [Merck's] Coppertone SPORT SPF 100+ Sunscreen Lotion label." (FAC ¶ 12.)

Plaintiff alleges that consumers have learned to associate higher SPF values with greater sun protection; consumers assume a product with an SPF of 100+ provides twice the protection against sunburn caused by ultraviolet B ("UVB") of a sunscreen product with an SPF of 50, when in fact products with SPF values of over 50 do not provide any increase in clinical benefit over SPF 50 sunscreen products. (FAC ¶ 3.) Plaintiff alleges that Merck's SPF 55, 70+, 80 and 100+ representations on its sunscreen products are therefore false, misleading, and reasonably likely to deceive the public. (FAC ¶ 3.) Plaintiff filed this action alleging violations of the Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 *et seq*. ("UCL") and the Consumer Legal Remedies Act, Cal. Civ. Code § 1750 *et seq.* ("CLRA"), and breach of express warranty under California common law. She seeks damages and injunctive relief for herself and a class of similarly situated individuals. Specifically, Plaintiff requests an order that Defendants charge the same price for SPF 50+ products as SPF 50 products, and/or that they include "a disclaimer on the label or packaging that a SPF value above 50 does not provide proportional clinical benefits." (*Id*. at 10-11 & 16.) Plaintiff further seeks an order requiring that Merck "engage in a corrective advertising campaign." (FAC, Prayer for Relief, ¶ E.) The Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332(d).

Defendants filed their motion to dismiss under Rule 12(b)(6), which tests the sufficiency of the complaint. *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). Dismissal is warranted where the complaint lacks a cognizable legal theory. *Shroyer v. New Cingular Wireless Serv., Inc.*, 622 F.3d 1035, 1041 (9th Cir. 2010) (internal quotation marks and citation omitted). Alternatively, a complaint may be dismissed where it presents a cognizable legal theory, yet fails to plead essential facts under that theory. *Robertson v. Dean Witter Reynolds, Inc.*,749 F.2d 530, 534 (9th Cir. 1984); *see also Shroyer*, 622 F.3d at 1041. In reviewing a Rule 12(b)(6) motion, the Court must

assume the truth of all factual allegations and construe them most favorably to the nonmoving party. *Huynh v. Chase Manhattan Bank*, 465 F.3d 992, 997 (9th Cir. 2006). However, legal conclusions need not be taken as true merely because they are couched as factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Similarly, "conclusory allegations of law and unwarranted inferences are not sufficient to defeat a motion to dismiss." *Pareto v. Fed. Deposit Ins. Corp.*, 139 F.3d 696, 699 (9th Cir. 1998).

Defendants argue Plaintiff's action is pre-empted by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). "In pre-emption cases, the question is whether state law is pre-empted by a federal statute, or in some instances, a federal agency action." *Pom Wonderful LLC v. The Coca-Cola Co.*, __ U.S. __, 134 S.Ct. 2228, 2236 (2014). Although it is presumed that Congress does not intend to displace state law,

> State action may nonetheless be foreclosed by express language in a congressional enactment, by implication from the depth and breadth of a congressional scheme that occupies the legislative field, or by implication because of a conflict with a congressional enactment.

Holmes v. Merck & Co., Inc., 697 F.3d 1080, 1085 (9th Cir. 2012) (internal quotation marks and citations omitted); *see also Arizona v. United States*, 567 U.S. __, 132 S.Ct. 2492, 2500-01 (2012). "Regardless of the type of preemption involved – express, field, or conflict – 'the purpose of Congress is the ultimate touchstone of pre-emption analysis.'" *Gilstrap v. United Air Lines, Inc.*, 709 F.3d 995, 1003 (2013), quoting *Cipollone v. Liggett Group., Inc.*, 505 U.S. 504, 516 (1992) (brackets omitted). The "task is to 'identify the domain expressly pre-empted by that language.' That task must 'in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.' We may find preemption only where it is the 'clear and manifest purpose of Congress.'" *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148 (9th Cir. 2010), quoting *Medtronic, Inc. v. Lohr*,

518 U.S. 470, 484 (1996); *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) & *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

The FDCA, which includes an express pre-emption statute, is unambiguous and broad in scope:

> no State ... may establish or continue in effect any requirement [¶] that relates to regulation of [OTC drugs]; and [¶] that is different from or *in addition to, or that is otherwise not identical with* a requirement under [the FTCA].

21 U.S.C. § 379r (emphasis added).

The current regulations establish labeling requirements, provide for effectiveness testing upon which the labeling relies, and identify false and misleading claims that render a product misbranded. 76 Fed. Reg. 35620-21 (Jun. 17, 2011) (*Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use*) ("Final Rule"). The Final Rule requires compliance with the regulation's labeling requirements, and embodies the Food and Drug Administration's ("FDA") "current determination on appropriate regulation on these aspects of sunscreens." *Id*. at 35620 & 35621.

Significantly, the regulations promulgated by the Final Rule *mandate* that OTC sunscreen labels state the SPF value resulting from the detailed testing procedure described in the regulation. 21 C.F.R. § 201.327(a)(1) & (I) (describing testing procedure to arrive at appropriate SPF values and providing labels "shall" state the SPF value). Merck argues its labeling simply complies with the FDA's mandate; it does no more than state the SPF value. In her opposition, Plaintiff argues her claim is not that SPF values above 50 are *per se* misleading, but that Merck "markets" its sunscreen products in a way that misleads consumers into believing that SPF values above 50 provide proportionally superior sun protection. (Opp'n at 10, citing FAC ¶¶ 6, 18 & 22.) Plaintiff argues the SPF values (55-100+) placed on Merck's sunscreen products, combined with premium pricing – a dollar or more for SPF 100+ than the same size

SPF 50 product – misleads consumers into believing they are purchasing proportionally superior sun protection, when they are not. (FAC ¶¶ 6 & 18.)

The problem with Plaintiff's argument, however, is that it expands the claim she has actually alleged. The essence of Plaintiff's claim is that "Merck's SPF 55, 70+, 80 or 100+ representations (the 'superior UVB protection claims') *on its Coppertone SPF 55-100+ collection* are false, misleading, and reasonably likely to deceive the public." (FAC ¶ 4) (emphasis added). There are no allegations that Plaintiff was exposed to anything other than Merck's sunscreen label on its products, that Merck was involved in any way in setting price or staging product at retail outlets, that Merck made any affirmative claims of proportionally greater UVB protection for SPF 50+ sunscreen products, or that Merck used misleading labels, such as "sunblock" or "waterproof."

Plaintiff argues she is not seeking "to disrupt existing federal regulations, but rather to provide greater consumer protections that are consistent with FDA regulations." (Opp'n at 15-16.) But in seeking to provide greater consumer protections, Plaintiff targets Merck's sunscreen label (which complies with current FDA regulations),[1] and proposes a disclaimer regarding the level of sunscreen effectiveness beyond SPF 50. Because the proposed disclaimer plainly adds to and is not identical with the FDA's requirements, Plaintiff's action is expressly pre-empted under 21 U.S.C. § 379r.[2]

Plaintiff's reliance on *Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207 (E.D. Cal. 2013) and *Lombardo v. Johnson & Johnson Consumer Companies*, case no.

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[1] Although Plaintiff specifically alleged Merck's sunscreen labeling ("SPF 55-100+") is false and misleading, (FAC ¶ 4), she has retreated from that assertion and now concedes that Merck's sunscreen labeling is not, standing alone, false or misleading. *See* Opp'n at 10 (Plaintiff does not claim that Merck's "SPF values on [its] Coppertone 50-100+ [sic]Products are themselves per se false or misleading.")

[2] Plaintiff also requests that the Merck Defendants be barred from charging a premium for sunscreens with SPF values above 50. As noted, the Merck Defendants are not retailers. And the FAC is devoid of any allegation that Merck sets the price charged by retailers, such as Wal-Mart, or that Merck dictates how its products are staged by retailers. Assuming such allegations, however, Plaintiff's requested relief would be precluded by the doctrine of primary jurisdiction, discussed below.

13-60536-Civ-Scola (S.D. Fla. Dec. 19, 2013 & Sep. 10, 2014), is unpersuasive. *Lombardo* is distinguishable, in part, as it involved labeling ("Waterproof Sunblock") that is squarely proscribed by the FDA. Moreover, neither *Corra* nor *Lombardo* considered whether a disclaimer regarding clinical benefits, as proposed by Plaintiff in the present case, would add to or be identical with the FDA's labeling requirements. *See Corra*, 962 F. Supp. 2d at 1215 ("If Plaintiff were to prevail under the UCL and CLRA, Defendants' SPF labeling duties would remain unchanged."); *Lombardo*, 13-60536-Civ-Scola, docket no. 47, at 6 ("labeling requirements would remain unchanged") & docket no. 75, at 5 ("Lombardo is not attempting to enforce any sort of state labeling requirement in addition to the Final Rule").

The Court also rejects Plaintiff's argument that 21 C.F.R. § 201.327(g) expressly permits actions alleging false or misleading labeling claims. The regulation is not as broadly worded as Plaintiff assumes. It provides:

> False and misleading claims. There are claims that would be false and/or misleading on sunscreen products. These claims include but are not limited to the following: "Sunblock," "sweatproof," and "waterproof." These or similar claims will cause the product to be misbranded under section 502 of the FD & C Act (21 U.S.C. § 352).

Although the regulation does not purport to provide an exclusive list of false and/or misleading claims, its scope is limited to claims *similar* to those listed. Plaintiff does not argue, nor could she, that premium pricing or the lack of a disclaimer regarding proportional clinical benefits of SPF 50+ products are similar to the claims precluded by the regulation. Defendants' motion to dismiss based on express pre-emption under the FDCA is therefore granted.

Defendant's motion is also granted on primary jurisdiction grounds. Primary jurisdiction is a prudential doctrine, which, under appropriate circumstances, provides that "the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *GCB Communications, Inc. v. U.S. South Communications, Inc.*, 650 F.3d 1257, 1263 (9th Cir.2011). The courts must defer to an administrative agency "where (1) the issue is not within the conventional experiences

of judges, (2) the issue involves technical or policy considerations within the agency's particular field of expertise, (3) the issue is particularly within the agency's discretion, or (4) there exists a substantial danger of inconsistent rulings." *Maronyan v. Toyota Motor Sales, U.S.A., Inc.*, 658 F.3d 1038, 1048–49 (9th Cir. 2011) (internal quotation marks and citation omitted). "[T]he doctrine is not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit[, but] is to be used only if a claim requires resolution of an issue of first impression, or a particularly complicated issue that Congress has committed to a regulatory agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114-15. (9th Cir.2008) (internal quotation marks and citation omitted).

Underlying all of Plaintiff's claims is the allegation that sunscreen products labeled above SPF 50 are clinically no more effective than SPF 50 products, and thus, labeling such products with values of 55-100+ is inherently misleading. The issue of any additional clinical benefit of sunscreen products with values above SPF 50 has been *pending* before the FDA since June 2011, when the FDA issued a proposed rule seeking comment and submission of data on this very issue. 76 Fed. Reg. 35672 (Jun. 17, 2011) (*Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use*) ("Proposed Rule"). While the FDA may be moving glacially, and ultimately, may come out the way Plaintiff urges in this action, that determination is underway and yet to be made. Through this action, Plaintiff invites the Court to weigh in, find in her favor, and take action by requiring Merck to make a disclaimer and engage in corrective advertising.

Exercising such jurisdiction over Plaintiff's claims presents substantial risk of inconsistent rulings on issues presently pending before the FDA.[3] The investigation of clinical benefits of drugs is particularly within the FDA's initial decisionmaking

[3] The timing of the Merck Defendants' marketing or labeling does not affect the potential for inconsistent findings on the clinical benefit issue. Accordingly, Plaintiff's oral request at the hearing to limit the time frame of her claim is denied.

domain, and is therefore not appropriate for adjudication before completion of the FDA's own decisionmaking process. The FDA regulations support this conclusion:

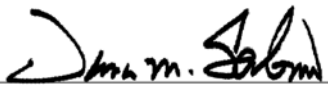
> FDA has primary jurisdiction to make initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if previously determined, the agency concluded should be reconsidered and subject to a new administrative determination.

21 C.F.R. §10.25. Plaintiff's reliance on *Corra* and *Lombardo* is unpersuasive because those courts did not consider the effect of 21 C.F.R. § 10.25 and did not analyze primary jurisdiction in the context of the FDA's pending decisionmaking process regarding the clinical benefit of SPF 50+ sunscreen products.

For the foregoing reasons, Defendants' motion to dismiss is granted. This action is dismissed without prejudice.

IT IS SO ORDERED.

DATED: November 25, 2014



HON. DANA M. SABRAW
United States District Judge